REMARKS

Upon entry of the amendments, claims 5 and 8-15 will be pending. Claim 7 has been allowed. Claims 1-4, 6, and 16-22 have been withdrawn.

Regarding the Amendments

Claim 5 has been amended to recite a polypeptide is further characterized as "having an amino acid sequence as set forth in SEQ ID NO: 2 or SEQ ID NO: 4.". The amendment is supported, for example, at page 7, paragraph 0031, through page 8, paragraph 0033. As such, it is submitted that the amendment to claim 5 does not add new matter.

Claim 8 has been amended to recite that a polynucleotide "specifically hybridizes under moderately to highly stringent conditions" and to further clarify the inventive subject matter. The amendment is supported, for example, at page 11, paragraph 0043, through page 12, paragraph 0044. As such, it is submitted that the amendments to claim 8 do not add new matter.

Claim 9 has been amended to clarify the subject matter regarded as the invention. The amendment is supported by the claim as originally filed. As such, it is submitted that the amendment to claim 9 does not add new matter.

Claim 10 has been amended to clarify the subject matter Applicant regards as the invention. The amendment is supported by the claim as originally filed. As such, it is submitted that the amendment to claim 10 does not add new matter.

Claim 12 has been amended to clarify that the "vector is a viral vector" of a vector as recited. The amendment merely addresses an informality and, therefore, does not add new matter.

Claim 13 has been amended to clarify that the "vector is a plasmid vector" of a vector as recited, and to more clearly depend from claim 11. The amendments merely addresses informalities and, therefore, does not add new matter.

Regarding the Election/Restrictions

Applicant acknowledges the election of Group II (claims 5 and 7-15) and withdrawal of claims from consideration by the Examiner as being drawn to non-elected inventions.

Regarding the Priority

It is stated in the Office Action that the sequences disclosed in the current application (non-provisional application 09/982,091) as SEQ ID NO: 3 and SEQ ID NO: 5 were not disclosed in the priority application (provisional application 60/241,246). Accordingly, the Examiner alleges that the priority application does not provide support for the claimed subject matter, and, therefore, to the extent that the claims read on SEQ ID NO: 3 and SEQ ID NO: 5, the claims are afforded a priority date of October 17, 2001.

Applicants submit, however, that the nucleotide sequence identified as SEQ ID NO: 3 is fully disclosed in U.S. Serial No. 60/241,246, filed October 17, 2000. The priority application discloses the nucleic acid sequence identified by GenBank accession number AF297866 at page 10, first full paragraph. The current application discloses that the human nucleic acid sequence identified as SEQ ID NO: 3 corresponds to GenBank accession number AF297866 (see, for example, page 5, paragraph 21; page 51, paragraph 156). As such, it is submitted that the currently pending claims, to the extent they read on SEQ ID NO: 3, are enabled by and described in U.S. Serial No. 60/241,246, filed October 17, 2000, and, therefore, entitled to the earliest priority.

Applicants further submit that the current claims reading on SEQ ID NO: 5 should also be afforded the October 17, 2000 priority date due to the close homology between SEQ ID NO: 5 and the sequences disclosed in the priority application. For example, SEQ ID NO: 3 and SEQ ID NO: 5 represent the nucleotide sequence and genomic sequence of human Claspin, respectively. The current specification describes homologous sequences and specifies that a degree of homology between sequences is a function of the number of matching or homologous positions shared by the sequences (see, for example, page 8, paragraph 0036). In this regard, the

sequences are highly homologous, for example, with respect to regions encoding regulatory sequences, start sites, and exons (see, for example, page 10, paragraph 0039). Furthermore, the priority application describes the location of the genomic sequence for human Claspin on chromosome 1 and discloses a GenBank entry for such a genomic sequence (see U.S. Serial No. 60/241,246, page 10, first full paragraph). As such, Applicants submit that, to the extent the current claims read on SEQ ID NO: 5, sufficient description is provided by homologous sequences disclosed in U.S. Serial No. 60/241,246, filed October 17, 2000, and, therefore, the claims are entitled to the earliest priority.

Rejections Under 35 U.S.C. § 112

The rejection of claim 5 under 35 U.S.C. § 112, first paragraph, for containing subject matter allegedly not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors had possession of the invention at the time the application was filed, is respectfully traversed.

In particular, the Examiner alleges that claim 5 lacks adequate written description because the claim is generic and the disclosure in the specification of "two homologous polypeptide sequences" allegedly fails to reflect the variation within the claimed genus. However, Applicants are unclear as to why the Examiner considers the disclosure insufficient, and what, other than the Examiner's enumeration of disclosed polypeptide sequences, would lead one skilled in the art to believe that Applicants were not in possession of a variety of species sufficient to describe the claimed genus. In this regard, it is noted that the Guidelines for Written Description, upon which the rejection is based, indicate that the number of disclosed species alone is not dispositive as to whether the disclosure is representative of a genus, and that "there may be situations where one species adequately supports a genus" (Federal Register, Vol. 66, No. 4, Column 3, page 1106; see also, MPEP § 2163). As such, it is submitted that the mere fact that two homologous polypeptides are disclosed in the specification does not support the Examiner's position that the genus is insufficiently described.

Regardless of the number of polypeptide species disclosed, it is submitted that one of skill in the art would recognize that Applicants were in possession of a representative number of species because the necessary common attributes or features of the elements possessed by members of the genus are described in the specification. The specification discloses a family of Claspin polypeptides involved in regulating progression of the cell cycle by specifically interacting with a Chk1 kinase protein, wherein the interaction of Claspin polypeptide with Chk1 allows phosphorylation and activation of Chk1 and subsequent arrest of the cell cycle, for example, in cells containing unreplicated or damaged DNA (see, for example, page 3, paragraph 0010; page 6, paragraph 0027-0028). Further, a comparison of Claspin polypeptides from two phylogenetically diverse organisms, Xenopus and human proteins, indicates that Claspin proteins have conserved nuclear localization signals and a large number of SQ/TQ motifs which are potential substrates for kinases involved in checkpoint pathways. The specification further discloses that the Claspin polypeptides are acidic polypeptides, having an isoelectric point of about 4.5 (see, for example, page 6, paragraph 0029, to page 7, paragraph 0031; and page 51, paragraph 0156 to page 52, paragraph 0157). As such, it is submitted that it would be clear to a skilled artisan, viewing the specification, that Applicants were in possession the common attributes or features of the elements possessed by members of the claimed genus and, therefore, a representative number of species.

Accordingly, in view of the above remarks, it is respectfully requested that the rejection of claim 5 for inadequate written description, due to insufficient disclosure of a representative number of species, be removed

It is also alleged in the Office Action that, beyond the disclosure of a representative number of species, claim 5 lacks sufficient written description because the structural limitations of the claim do not define a protein having any specific function; because "it is not sufficient to define a polypeptide solely by its principle biological property," as is alleged in the instant case; and because there is no disclosed correlation between function and structure. It is noted that the

language of Guidelines for Written Description, cited by the Examiner, states that "the written description requirement for a claimed genus may be satisfied...by disclosure of relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with known or disclosed correlation between function and structure, or by a combination of such identifying characteristics..." (Federal Register, Vol. 66, No. 4, Column 3, page 1106. Emphasis added).

Applicants submit that it is the combination of functional and structural elements, or identifying characteristics, disclosed in the specification and recited in the claims that sufficiently show that Applicants were in possession of the claimed genus. As discussed above, the specification discloses a family of Claspin polypeptides that interact with a Chk1 kinase protein, allowing phosphorylation and activation of Chk1 and arrest of the cell cycle. A comparison of different species of polypeptides identifies conserved nuclear localization signals, a large number of SQ/TQ motifs, and the acidic nature of the polypeptides of the invention, characterized as having an isoelectric point of about 4.5. As such, it is respectfully submitted that these identifying characteristics, when taken in combination, meet the written description requirement such that a skilled artisan would have known that applicant was in possession of the genus of claimed polypeptides.

It is further submitted that a correlation between the functional and structural elements of the claimed polypeptides would have been recognized by one skilled in the art viewing the specification. For example, the specification discloses that the polypeptides of the invention contain relatively large number of SQ/TQ motifs, and the serines and threonines in this type of motif are known in the art to be potential substrates for phosphorylation by kinases known to be involved in checkpoint pathways. The specification further characterizes the interaction of the polypeptides of the invention with Chk1 proteins and discloses that phosphorylation of Claspin is required for binding to Chk1 proteins. As such, it is submitted that one skilled in the art would recognize a correlation between SQ/TQ motifs and the phosphorylation required for the interaction of the claimed polypeptides and Chk1 proteins involved in cell cycle regulation.

However, in order to advance prosecution, claim 5 has been amended to include a polypeptide having an amino acid sequence as set forth in SEQ ID NO: 2 or SEQ ID NO: 4. Therefore, it is respectfully submitted that the functional and structural identifying characteristics disclosed in the specification and recited in claim 5, when taken together, meet the written description requirement and that one of skill in the art would have known, from the combination of these elements, that applicant was in possession of the genus of claimed polypeptides. Accordingly, it is respectfully requested that the rejection of claim 5 under 35 U.S.C. § 112, first paragraph, for lack of sufficient written description be removed.

The rejection of claims 8-9 and 11-15 under 35 U.S.C. § 112, first paragraph, as allegedly lacking adequate written description, is respectfully traversed.

In particular, the claims are rejected for reciting the term "having" in claims 8-9; it is alleged that the claims encompass polynucleotides comprising 15 continuous bases that hybridize with sequences not disclosed in the specification. The Examiner has recommended replacing the term "having," as recited in claims 8-9, with "consisting of."

It is initially noted that claims 8 and 9 have been amended, and Applicants submit that this issue is moot. As amended, claim 8 is directed to an isolated polynucleotide "having at least 15 contiguous bases that specifically hybridizes under highly stringent conditions" to a polynucleotide having a nucleotide sequences as set forth in the claim. As such, claim 8 has been amended in order to clarify that hybridization of the polynucleotide fragment is dependent upon the presence of 1) a polynucleotide encoding SEQ ID NO: 2 or SEQ ID NO: 4; 2) a nucleotide sequence as set forth in SEQ ID NO: 1; or 3) variants of 1) and 2) as specified in the claim. However, the claimed polynucleotide is not strictly limited to those exact sequences.

With respect to the polynucleotides to which a claimed polynucleotide fragment can specifically hybridize, Applicants do not agree with the Examiner's position that the claims should be limited to the exact sequences as set forth in the sequence listings, and Applicants submit that the specification provides ample support for polynucleotides "having" the disclosed

sequences. In this regard, it is noted that the specification provides numerous examples where polynucleotides of the invention can include additional nucleotide sequences including (see, for example, page 9, paragraph 0038). Exemplified embodiments include, for example, incorporation within a vector (see, for example, pages 12-19) sequences encoding peptides useful for recovering the peptides for a host cell (page 19, paragraph 0062), a protease site, a tag peptide, secretory peptide, or the like (page 20, paragraph 0063), restriction endonuclease recognition and cleavage sites, selective recognition domain, spacer element. Thus, when the claims are construed in view of the specification, those skilled in the art would readily recognize that the specification provides sufficient information to demonstrate possession of the presently claimed polynucleotides. As such, it is respectfully requested that this ground of the rejection be removed.

It is also alleged in the Office Action that claims 8-9 and 11-15 lack adequate written description because the claims do not specify hybridization conditions. Claims 8-9 have been amended, thereby rendering this rejection moot. In particular, the Examiner's attention is drawn to Claim 8, which has been amended to recite that the claimed polynucleotide fragment hybridizes "under highly stringent conditions." As such, it is respectfully requested that this ground of the rejection be removed.

The rejection of claim 10 under 35 U.S.C. § 112, first paragraph, as allegedly lacking adequate written description, is respectfully traversed.

It is alleged by the Examiner that claim 10, part (c), lacks adequate written description because the antecedent basis for the fragment is a polynucleotide comprising a disclosed sequence and the claim allegedly encompasses fragments of a polynucleotide that are not disclosed in the specification. The claim has been amended to clarify the subject matter regarded as the invention. As such, removal of this rejection is respectfully requested.

The rejection of claims 8-15 under 35 U.S.C. § 112, first paragraph, as allegedly lacking enablement, is respectfully traversed.

It is acknowledged in the Office Action that the specification is enabling for nucleic acids encoding Claspin polypeptides and fragments thereof of sufficient size to encode epitopes or act as specific probes for nucleic acids encoding Claspin polypeptides. It is alleged, however, that the specification does not provide enablement for all polynucleotides comprising 15 continuous bases that hybridize with some undisclosed sequence; any polynucleotide that comprises 15 continuous bases that hybridize to one of the disclosed sequences; or fragments of undisclosed sequence.

Applicants point out that, as noted above, the claims have been amended. In particular, claim 8 has been amended to clarify that the polynucleotide fragment useful in the claimed methods "specifically hybridizes under highly stringent conditions." Amended claim 9 is directed to an isolated polynucleotide comprising the nucleotide sequences as set forth in the claim and disclosed in the specification. Therefore, it is submitted that current claims 8-9, and 11-15 are directed to either polynucleotides encoding Claspin polypeptides, or fragments thereof of sufficient size to encode epitomes or act as specific probes for polynucleotides encoding Claspin polypeptides, which is subject matter that the Examiner specifically acknowledges as enabled by the specification.

With regard to claim 10, it is alleged that the specification does not provide a specific or substantial use for fragments of SEQ ID NO: 5 of all lengths. As noted above, the claim has been amended, thereby rendering this issue moot. Accordingly, it is respectfully requested that this rejection be removed.

As such, it is submitted that one skilled in the art, viewing the specification, would have known how to practice the claimed methods without undue experimentation. Accordingly, reconsideration and removal of the rejection of the claims under 35 U.S.C. 112, first paragraph, are respectfully requested.

The rejection of claims 12-13 under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite is respectfully traversed.

It is alleged that the terms "virus derived" in claim 12 and "plasmid derived" in claim 13 are indefinite because the claims do not recite some starting material. The claims have been amended to clarify the expression vectors of the claims. As such, it is respectfully requested that this rejection be removed.

Claim 13 is additionally rejected for being allegedly indefinite for improperly depending on claim 12. Claim 13 has been amended to depend from claim 11, as suggested by the Examiner. Accordingly, removal of this rejection is respectfully requested.

Rejections Under 35 U.S.C. § 102

The rejection of claims 8-10 under 35 U.S.C. § 102(a) as being anticipated by the sequence set forth as Accession No. AL354864 (April 4, 2001) is respectfully traversed.

It is stated in the Office Action that the sequence set forth as Accession No. AL354864 teaches a sequence of at least 15 bases that hybridizes to a polynucleotide having the nucleotide sequence set forth in the current application as SEQ ID NO: 3. Applicants point out, however, that claims 8-9 have been amended, thereby rendering the rejection moot with respect to these claims.

It is further noted that anticipation under 35 U.S.C. § 102(a) requires that "the invention was known or used by others in this country, or patented...before the invention thereof by the applicant for patent." For the reasons set forth above, it is submitted that, with respect to at least SEQ ID NO: 3, the claimed invention is entitled to the October 17, 2000, priority date of U.S. Serial No. 60/241,246. As such, Accession No. AL354864, which is dated April 4, 2001, is not prior art under 35 U.S.C. § 102 with respect to SEQ ID NO: 3 of the claimed invention. Accordingly, it is respectfully requested that this ground of the rejection under 35 U.S.C. § 102(a) be removed.

Regarding claim 10, it is further stated in the Office Action that the sequence set forth as Accession No. AL354864 teaches a sequence that is a fragment of SEQ ID NO: 5. As discussed above, however, it is submitted that, with respect to at least SEQ ID NO: 5, the claimed invention is entitled to the October 17, 2000, priority date of U.S. Serial No. 60/241,246. As such, Accession No. AL354864, which is dated April 4, 2001, is not prior art under 35 U.S.C. § 102 with respect to SEQ ID NO: 5 of the claimed invention. Regardless of the afforded priority date, however, claim 10 has been amended, thereby rendering the rejection moot. As such, removal of the rejection is respectfully requested.

The rejection of claims 8-10 under 35 U.S.C. § 102(b) as being anticipated by the sequences set forth as Accession No. AP001261 (May 30, 2000) or Accession No. G30470 (1996) is respectfully traversed.

It is stated in the Office Action that the sequences set forth as Accession No. AP001261 and Accession No. G30470 teach a sequence of at least 15 bases that hybridizes to a polynucleotide having the nucleotide sequence set forth in the current application as SEQ ID NO: 3 and a sequence that is a fragment of SEQ ID NO: 5. However, the claims have been amended, thereby rendering the rejection moot.

Applicants further note that anticipation under 35 U.S.C. § 102(b) requires that "the invention was patented or described in a printed publication...more than one year prior to the date of the application for patent" (Emphasis added). For the reasons set forth above, it is submitted that, with respect to SEQ ID NO: 3 and SEQ ID NO: 5, the claimed invention is entitled to the October 17, 2000, priority date of U.S. Serial No. 60/241,246. As such, Accession No. AP001261, which is dated May 30, 2000, does not qualify as prior art under 35 U.S.C. § 102(b) with respect to SEQ ID NO: 3 and SEQ ID NO: 5 of the claimed invention.

Accordingly, in view of the amendments and above remarks, it is respectfully requested that the rejection of claims 8-10 under 35 U.S.C. § 102(b) be removed.

The Examiner is invited to contact Applicants' undersigned representative if there are any questions relating to this application. No fee is due in connection with this response. If any fee is due in connection with the filing of this response, the Commissioner is authorized to charge any fee (or credit any overpayment) to Deposit Acct. No. 50-1355.

Respectfully submitted,

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